



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,444	12/30/2003	Orla McCullagh	S63.2B-10954-US01	2373
60117	7590	09/12/2006	EXAMINER	
RATNER PRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,444

Applicant(s)

MCCULLAGH ET AL.

Examiner

Thomas J. Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/04 and 5/16/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species H, fig. 9, claims 1-33 in the reply filed on 07/21/2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Regarding claims 30, 31 and 33, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 33 contains the trademark/trade name BAYHDOL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyurethane dispersions and, accordingly, the identification/description is indefinite.

Claims 9 and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These are an improper Markush claims, which are not claimed

in the alternative (i.e. "select from at least one member" suggest plural member can be selected). Additionally, "heparin" is listed twice in claim 30, lines 3 and 10.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is an improper Markush claim, which does not claim in the alternative or use the terminology "selected from the group consisting of". Additionally, Markush groups cannot encompass redundant members (i.e. hybrid expandable and any combination thereof are the same/overlap).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 32 recites the broad recitation cells of human origin, and the claim also recites autologous or allogeneic (not and/or) which is the narrower statement of the range/limitation. In the present instance, claim 32 recites the broad recitation cells of non-human origin, and the claim also recites xenogeneic which is the narrower

Art Unit: 3738

statement of the range/limitation. Both instances assume a human is the recipient species, which is not claimed.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Line 14 claims "alone or together with other molecules" which is not claimed in the alternative and the scope of which cannot be discerned.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank et al (US 6231581). Shank et al discloses a stent (such as figs. 36 or 37) comprising: a first section (42a in e.g. fig. 26 or fig. 3), a second section (42b in e.g. fig. 26 or fig. 3) and at least one securement member (42a in e.g. fig. 26 or fig. 3), the at least one securement (52 in e.g. or 30 in fig. 3) member disposed about at least one region of the first section and at least one region of the second section (as shown), the at least one securement member having an uncrimped diameter and a crimped diameter (Col 10, lines 23-27 for fig. 26 or is fully capable of having an uncrimped diameter prior to the crimped diameter of 30 shown in fig. 3, since this is a product by process limitation and 30 meets the final crimp diameter which could be formed by crimping, the limitation is met), the crimped diameter being less than the uncrimped diameter, when the at least one securement member is in the crimped diameter at least a portion of an inner surface of

Art Unit: 3738

the at least one securement member is fixedly engaged (by compression or frictional contact) to the at least one region of the first section and the at least one region of the second section, in the crimped diameter the at least one region of the first section and the at least one region of the second section being immediately adjacent one another.

With regard to claim 2, at least one of the first section and second section is at least partially constructed of at least one wire (42 is wire).

With regard to claim 3, at least one of the first section and second section is at least partially constructed of a plurality of struts, wherein adjacent struts define at least one cell opening (such as shown in figs. 2, 36 and 37).

With regard to claim 4, at least one region of the first section and the at least one region of the second section define a seam therebetween (the 42s' define a seam since they are joined).

With regard to claim 5, at least a portion of the at least one region of the first section and at least a portion of the at least one region of the second section comprise at least one weld along the seam (col 4, lines 61-62 and col 1, lines 65-67).

With regard to claims 6-9, at least a portion of the at least one region of the first section and at least a portion of the at least one region of the second section are fused together along the seam (42a, 42b and 52 or 30 are welded/fuses together).

With regard to claim 10, at least one strengthening member, at least a portion of the at least one strengthening member (29, fig. 3) positioned between the at least a portion of an inner surface of the at least one securement member (30) and the at least one portion of at least one of the at least one region of the first section (42a) and the at least one region of the second section (42b).

With regard to claim 11, at least one weld is positioned between the at least a portion of the inner surface of the at least one securement member the at least one portion of at least one of the at least one region of the first section and the at least one region of the second section, and the at least a portion of the at least one strengthening member (col 1, lines 65-67).

With regard to claim 12, The stent of claim 1 further comprising at least one strengthening member (29, fig. 3), the at least one strengthening member comprising a first portion and a second portion, the first portion of the at least one strengthening member positioned between the at least a portion of an inner surface (hidden in fig. 3) of the at least one securement member and at least one portion of at least one of the at least one region of the first section and the at least one region of the second section, the second portion extending beyond an end of the at least one securement member (the portion of 29 extending out in fig. 3).

With regard to claim 13, at least one of the first portion and the second portion of the at least one strengthening member has a length of about 2 mm (Shank et al discloses about 2mm, which is applicable to fig. 3, col 8, lines 46-47).

With regard to claims 14 and 20-23, Shank et al discloses the use of nitinol and stainless steel (col 5, line 13).

With regard to claims 15 and 24, Shank et al discloses of radiopaque materials (col 13, lines 37-46).

With regard to claims 16 and 17, the at least one strengthening member has a thickness, the thickness being about 0.015 inches (Shank et al discloses a dimension, col 8, line 44 which can be categorized as thickness).

With regard to claim 18, Shank et al discloses self-expandable (col 1, lines 20-51 and col 12, lines 29-41) which is also inherently balloon expandable as well.

With regard to claim 19, the first section (42a) is a balloon expandable stent body and the second section (42b) is a self-expandable stent body (both are self-expandable which is inherently and fully capable of being balloon expandable as well since it is well known to seat a stent, filter, etc using a balloon after self-expansion).

With regard to claim, 25 and 26, Shank et al discloses a thickness being about 0.003 to about 0.007 inches (col 5, line 16).

With regard to claim 27, a third section (Col 10, lines 21-23), the at least one securement member (52) disposed about the at least one region of the first section (42a), the at least one region of the second section (42b), and at least one region of the third section, when the at least one securement member is in the crimped diameter the at least a portion of the inner surface of the at least one securement member is fixedly engaged to the at least one region of the first section, the at least one region of the second section and the at least one region of the third section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank et al in view Brown et al (US Pgpub 20030139798). Shank et al discloses a stent as discussed above.

Art Unit: 3738

However, Shank et al remains silent as to including a therapeutic coating on the stent. It is well known in the art of vascular implants (i.e. stent, etc.) to include a therapeutic polymer coating for the purpose of treating the vessel with medicament at the point of implantation as demonstrated by Brown et al [0044]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporated a therapeutic polymer coating such as taught by Brown et al on the stent of Shank et al in order to provide medicament at the point of implantation in the vessel.

With regard to claims 30-32, Brown et al discloses the use of non-genetic agent, genetic agent and cells [0044]. Such agents are well known in the art of vascular implants (i.e. stent, etc.) and include for example heparin, DNA (which include the antisense portion of DNA), and donor cells (which inherently includes autologous, allogeneic, and/or xenogeneic cells).

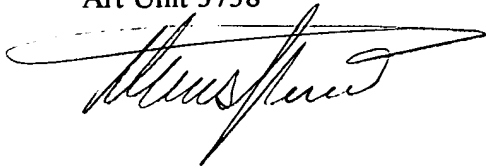
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner
Art Unit 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', with a long horizontal flourish extending to the left.